

Customer No.: 07278

Docket No.: 04266/100J959-US2

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Fausto BONIFACIO, et al.

Serial No.: TBA (Divisional of 10/214,386)

Filed: Concurrently Herewith

For: **NOVEL CRUDE AND CRYSTALLINE FORMS OF LERCANIDIPINE  
HYDROCHLORIDE**  
-----

February 18, 2004

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- ☒ A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- ☐ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before the mailing date of a final rejection, a notice of allowance, or any other action that closes prosecution, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ ii. A check for the fee set forth in 1. 17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Counsel states that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ i. A check for the fee set forth in 1.17 (p), presently believed to be \$180, is enclosed.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

- ☒ A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patents and published Patent Applications on PTO/SB08 is/are not being submitted.
- ☐ B. Document(s) \_\_\_\_\_ is (are) deemed substantially cumulative to document(s) \_\_\_\_\_, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☒ C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

Serial No. 10/214,386, filed August 6, 2002

Applicant Identifies these documents by attaching hereto copies of the forms PTO-892 and PTO/SB08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be

considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

[X] 3. Document(s) 20 is not in the English language. In accordance with 1.98(c), Applicant states:

- [X] A corresponding English-language patent, U.S. Patent No, 4,285,955, is enclosed.
- [] A concise explanation of the relevance of document(s) \_\_\_\_\_ is found in the attached search report (see MPEP § 609 A(3)x).
- [] A concise explanation of the relevance of document(s) \_\_\_\_\_ is set forth as follows: [Insert concise explanation of relevance]
- [] A concise explanation of the relevance of document(s) \_\_\_\_\_ can be found on page(s) \_\_\_\_\_ of the specification.
- [] A concise explanation of document(s) \_\_\_\_\_ can be found on the attached sheet.

[] 4. No explanation of relevance is necessary for documents in the English language (see MPEP § 609 A(3)).

[X] 5. Other information being provided for the examiner's consideration follows:  
An International Search Report, dated November 18, 2002, which issued during the prosecution of International Application No. PCT/EP02/08699 which corresponds to the present application.

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

**CROSS REFERENCE UNDER 37 C.F.R. §1.78 TO RELATED APPLICATIONS**

Pursuant to 37 C.F.R. § 1.78, Applicant notes that the above-identified patent application may be related to the following U.S. Patent Application:

(1) U.S. Patent Application Serial No 10/214,385, filed August 6, 2002, published as U.S. Patent Publication US 2003/0069285 A1.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mitchell Bernstein", written over a horizontal line.

Mitchell Bernstein, Ph.D.

Registration No. 46,550

Attorney for Applicant(s)

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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	TBA (Divisional of 10/214,386)
				Filing Date	Concurrently Herewith
				First Named Inventor	Fausto BONIFACIO
				Art Unit	TBA
				Examiner Name	TBA
Sheet	1	of	1	Attorney Docket Number	04266/100J959-US2

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	1.	US 2003/0069285 A1	04/10/2003	Amedeo LEONARDI	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

**Complete if Known**

Application Number	US 10/214,386
Filing Date	Aug. 6, 2002
First Named Inventor	Bonifacio et al.
Group Art Unit	TBA
Examiner Name	TBA
Attorney Docket Number	4266/1J959-US1

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	1.	US- 4,285,955	08-25-1981	Wehinger et al.	
	2.	US- 4,705,797	11-10-1987	Nardi et al.	
	3.	US- 4,968,832	11-06-1990	Nardi et al.	
	4.	US- 5,248,699	09-28-1993	Sysko et al.	
	5.	US- 5,696,139	12-09-1997	Leonardi et al.	
	6.	US- 5,767,136	06-16-1998	Sartani et al.	
	7.	US- 5,912,351	06-15-1999	Leonardi et al.	
	8.	2001/0002404	05-31-2001	Webb et al.	
	9.	2001/0029257	10-11-2001	Murdock et al.	
	10.	2001/0044584	11-22-2001	Kensey	
	11.	2002/0010208	01-24-2002	Shashoua et al.	
	12.	2002/0015713	02-07-2002	Murdock et al.	
	13.	2002/0032149	03-14-2002	Kensey	
	14.	2002/0042405	04-11-2002	Schuh	
	15.	2001/0056095	12-27-2001	Mylari	
	16.	2002/0061835	05-23-2002	Kensey	
	17.	2002/0068740	06-06-2002	Mylari	
	18.	2002/0099046	07-25-2002	Scott	
	19.	2002/0137755	09-26-2002	Bilodeau et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	20.	DE 28 47 237	05-14-1980	Bayer AG		X
	21.	EP 0 153 016	05-16-1990	Recordati S.A. Chemical and Pharmaceutical Company		
	22.	WO 96/35668	11-14-1996	Recordati S.A. Chemical and Pharmaceutical Company		
	23.	WO 97/03669	02-06-1997	Recordati S.A. Chemical and Pharmaceutical Company		

Examiner  
SignatureDate  
Considered

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Approved for use through 10/31/2002. OMB 0651-0031  
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Substitute for form 1449A/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	US 10/214,386
				Filing Date	Aug. 6, 2002
				First Named Inventor	Bonifacio et al.
				Group Art Unit	TBA
				Examiner Name	TBA
Sheet	2	of	2	Attorney Docket Number	4266/1J959-US1

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	24.	Leonardi et al. (1998) "Asymmetric N-(3,3-diphenylpropyl)aminoalkyl esters of 4-aryl-2,6-dimethyl-1,4-dihydropyridine,-3,5-dicarboxylic acids with antihypertensive activity", <i>Eur. J. Med. Chem.</i> , 33:399-420	
	25.	McClellan and Jarvis, (2000) "Lercanidipine: A Review of its Use in Hypertension", <i>Adis Drug Evaluation</i> , 60:1123-1140	
	26.	(1987) REC 15/2375, <i>Drugs of the Future</i> , 12:1113-1115	

Examiner Signature		Date Considered	
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